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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,597	01/07/1999	JULIO PIMENTEL	585-017-84	9844

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PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	23

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Reconsideration

1. Applicant's request for reconsideration filed 8/21/02 in Paper No. 22 is acknowledged and has been entered. Currently, claims 1-9 are pending and remain under examination.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reason of record and reiterated as follows.

Claim 1 remains vague and indefinite. Specifically, the preamble in claim 1 recites a method for inhibiting body weight gained after eating but the body of the claim does not set forth any limitation encompassing how inhibiting the amount of body weight gained is effected. Specifically, while claim 1 recites, "feeding to an animal an effective amount of a liposome-encapsulated immunoglobulin against lipase", it is unclear how such an *effective amount* enables inhibition of body weight gained. For example, does Applicant intend an effective amount of liposome-encapsulated immunoglobulin against lipase to bind lipase in the gut; thus inhibiting weight gained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

3. Claims 1-9 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for reason of record.

Scope of Enablement

4. Claims 1-9 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method that reduces the amount of body weight gained in rats after eating a high fat diet, does not reasonably provide enablement for a method that inhibits the amount of body weight gained in any and all animals after eating as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is being maintained for reason of record.

Enablement

5. Claims 1-9 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the mode of release, location of release, and the viability of the encapsulated immunoglobulins against lipase after release from liposomes, so as to inhibit weight gain to enable claim 1 are not described in the specification. The mode of action and function of immunoglobulins against lipase in relation to lipase antigen, in order to inhibit weight gain in any and all animals as required by claim 1 is not described in the specification. The structure of lipase antigen from which antilipase antibodies are generated from, so as to enable interspecies cross-reactivity, i.e. mammalian and avian, for use in totally inhibiting weight gain in any animal to enable claim 1, is not characterized and fully described in the specification. This rejection is being maintained for reason of record.

Response to Arguments

6. Applicant's arguments filed 8/21/02 have been fully considered but they are not persuasive.

A) Applicant argues that while the assays did employ high fat diets, that does not mean that the test results are meaningless for normal diets. Applicant further contends that extra fat would have made it harder to prevent weight gain, so that the fact that the

method works even in the presence of fat in itself is evidence that the method is highly effective.

In response, the issue at hand is not whether test results in the specification are deemed to be meaningless, but that there is nowhere in the specification that supports the breadth of the claims, for scope and for applicability. As set forth in the previous Office Action, the specification does not provide evidentiary showing that the claimed invention will work on any type of diet other than high fat diet, nor does it establish a direct correlation between high fat diet and any and all types of high caloric diet, to render the method effective for all types of high caloric diet, so as to reasonably apprise to one skilled in the art of the scope of the claimed invention. The specification further does not provide any working examples of the claimed method to work in animals that have been fed a non-regulated diet, i.e. any diet other than a high fat diet. While it is not necessary to show working examples for every possible embodiment, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed method is enabled. This is not the case in the instant specification.

Additionally, Applicant's contention that, the fact that the method works even in the presence of fat in itself is evidence that the method is highly effective (for any type of diet), is without merit. General knowledge on lipase is that it plays a role in the breakdown and storage of fat but plays no role in the breakdown and storage of sugars, protein, and carbohydrates. It is, therefore, unlikely that the claimed method would work in an animal that was fed a diet high in sugars, protein, and carbohydrates because

anti-lipase immunoglobulin would have no effect on the breakdown and storage of sugars, protein, and carbohydrates.

B) Applicant further contends that the Richardson Declaration submitted on October 24, 2001, provides that the data in the specification represents a scientifically sound method for testing the invention, wherein high fat content is used in order to give a more clearly measurable result due to the weight enhancing properties of fat, than standard diet would have required.

Contrary to Applicant's argument, the issue at hand is not that the data in the specification is not scientifically sound for testing the invention, but that the breadth of the claimed invention encompasses a diet high in sugars, protein, and carbohydrates, yet the specification does not provide evidentiary showing of established correlation or analogous results, or even a working example of why the invention should also work for these high caloric diets, i.e. high sugar content, high protein content, high starch content, so as to encompass the breadth of the claimed invention. General knowledge on lipase is that it plays a role in the breakdown and storage of fat but plays no role in the breakdown and storage of sugars, protein, and carbohydrates. With that in mind, it is unlikely that the claimed method would work in an animal that was fed a diet high in sugars, protein, and carbohydrates because anti-lipase immunoglobulin would have no effect on the breakdown and storage of sugars, protein, and carbohydrates. Thus, the animal would still gain weight when fed the liposome encapsulated anti-lipase

immunoglobulin. The claimed method is, therefore, only enabled for animals, specifically rats, that have been fed a high fat diet.

Prior Art

7. Currently, claims 1-9 are clear of prior art.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gail Gabel
Patent Examiner
Group 1641

12/31/02

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641